

DEPARTMENT OF COMMERCE, COMMUNITY, AND ECONOMIC DEVELOPMENT  
DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING

# BOARD OF PHARMACY

CONDENSED MINUTES OF THE MEETING HELD (JUNE 16, 2022)

Date:	June 16, 2022
Time:	Scheduled @ 9:00 a.m.; actual start @ 9:30 a.m.
Location:	Zoom & Anchorage – Robert Atwood Building, Suite 1550, 500 W. 7 <sup>th</sup> Ave, Anchorage, AK 99501
Attending:	Board Members: Justin Ruffridge, Ashley Schaber, Ramsey Bell, Leif Holm, James Henderson. Staff: Laura Carrillo, Bradley Johnson, Charley Larson, Lisa Sherrell, Michael Bowles, Melissa Dumas
Absent:	

<b>Topic: Roll Call</b>		
Brief Discussion:	N/A	
Motion:	N/A	
Recorded Votes:	<i>Justin Ruffridge</i>	<i>James Henderson (not yet present)</i>
	Ashley Schaber	
	Ramsey Bell	
	Leif Holm	
Action Items:	N/A	
<b>Topic: Approve Agenda</b>		
Brief Discussion:	<i>The board reviewed the agenda for June 16, 2022.</i>	
Motion:	<ul style="list-style-type: none"> <li>• <i>Ashley Schaber motions to approve the agenda as written, seconded by Ramsey Bell, and approved unanimously. It is:</i></li> </ul> <p style="text-align: center;"><i>RESOLVED to approve the June 16, 2022 agenda as written.</i></p>	
Recorded Votes:	<i>Justin Ruffridge</i>	<i>James Henderson (not yet present)</i>
	Ashley Schaber	
	Ramsey Bell	
	Leif Holm	
Action Items:	N/A	
<b>Topic: Ethics disclosures</b>		

Brief Discussion:	<i>Ashley Schaber: member of the AKPhA and legislative committee. Justin Ruffridge: candidate for state house</i>	
Motion:	<i>N/A</i>	
Recorded Votes:	<i>N/A</i>	
Action Items:	<i>N/A</i>	
<b>Topic: Draft minutes</b>		
Brief Discussion:	<i>The board reviewed the draft minutes from February 17-18, 2022 and the motion list from March 25, 2022.</i>	
Motion:	<i>Ashley Schaber motions to approve the minutes as written, seconded by Ramsey Bell, and approved unanimously. It is:  RESOLVED to approve the February 17-18, 2022 draft minutes.</i>	
Recorded Votes:	<i>Justin Ruffridge</i>	<i>James Henderson (not yet present)</i>
	<i>Ashley Schaber</i>	
	<i>Ramsey Bell</i>	
	<i>Leif Holm</i>	
Action Items:	<i>Ms. Carrillo will send the February 2022 meeting minutes to Dr. Ruffridge and will request the final minutes be posted on the board's website.</i>	
<b>Topic: PDMP Update</b>		
Brief Discussion:	<i>Lisa Sherrell provides an update on: project assistant recruitment, communication module, data sharing with 17 states and Military Health System and configuring settings to include other jurisdictions in searches, delegate audit, awareness and feedback questionnaire highlights, statewide integration, consultant/analysis of PDMP, data overview (registration and reporting), reporting compliance monitoring.</i>	
Motion:	<i>N/A</i>	
Recorded Votes:	<i>N/A</i>	
Action Items:	<i>N/A</i>	
<b>Topic: INV Update</b>		
Brief Discussion:	<i>The board reviewed the report from February 8, 2022 through June 2, 2022. Investigator Bowles opened 36 cases and closed 12.</i>	

Motion:	<p><i>On a motion duly made by Ashley Schaber in accordance with AS 44.62.310(c)(2) and seconded by James Henderson, the board unanimously moves to enter executive session for the purpose of discussing subjects that tend to prejudice the reputation and character of any person, provided the person may request a public discussion. No request was made for public discussion. It is:</i></p> <p style="text-align: center;"><i>RESOLVED to enter into executive session in accordance with AS 44.62.310(c)(2). Staff, Michael Bowles, Laura Carrillo, Bradley Johnson, Lisa Sherrell, and Carmen Pora are authorized to remain in the room.</i></p> <p><i>Off record for executive session at 10:08 a.m.</i>  <i>On record from executive session at 10:32 a.m.</i></p>
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Recorded Votes:	<i>Justin Ruffridge</i>	<i>James Henderson</i>
	<i>Ashley Schaber</i>	
	<i>Ramsey Bell</i>	
	<i>Leif Holm</i>	

Motion:	<ul style="list-style-type: none"> <li>• <i>Ramsey Bell motions to accept the imposition of civil fine for 2021-001208 in the amount of \$300, seconded by James Henderson, and approved with one abstention by Ashley Schaber, it is:</i> <p style="text-align: center;"><i>RESOLVED to accept the imposition of civil fine for 2021-001208.</i></p> </li> <li>• <i>Ramsey Bell motions to accept the imposition of civil fine for 2021-000940 in the amount of \$250, seconded by James Henderson, and approved with one abstention by Ashley Schaber, it is:</i> <p style="text-align: center;"><i>RESOLVED to accept the imposition of civil fine for 2021-000940.</i></p> </li> <li>• <i>Ramsey Bell motions to accept the imposition of civil fine for 2021-001079 in the amount of \$250, seconded by James Henderson, and approved with one abstention by Leif Holm, it is:</i> <p style="text-align: center;"><i>RESOLVED to accept the imposition of civil fine for 2021-001079.</i></p> </li> <li>• <i>Ramsey Bell motions to accept the imposition of civil fine for 2021-001195 in the amount of \$300, seconded by James Henderson, and approved unanimously, it is:</i> <p style="text-align: center;"><i>RESOLVED to accept the imposition of civil fine for 2021-001195.</i></p> </li> <li>• <i>Ramsey Bell motions to accept the imposition of civil fine for 2021-000733 in the amount of \$500, seconded by James Henderson, and approved with one abstention by Leif Holm, it is:</i> <p style="text-align: center;"><i>RESOLVED to accept the imposition of civil fine for 2021-000733.</i></p> </li> </ul>
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	<ul style="list-style-type: none"> <li>Ramsey Bell motions to accept the imposition of civil fine for 2021-000187 in the amount of \$300, seconded by James Henderson, and approved with one abstention by Ashley Schaber, it is:  RESOLVED to accept the imposition of civil fine for 2021-2021-000187.</li> </ul>	
Recorded Votes:	Justin Ruffridge	James Henderson
	Ashley Schaber	
	Ramsey Bell	
	Leif Holm	
Action Items:	Dr. Ruffridge will send the signed imposition of civil fines to Investigator Bowles.	
<b>Topic: Public Comment</b>		
Brief Discussion:	<p>Callista Carlton: requests language addressing kiosk placement (at least 10 feet from pharmacy)</p> <p>Brandy Seignemartin (AKPHA): thanks the board for their collaboration on HB 145.</p>	
Motion:	N/A	
Recorded Votes:	N/A	
Action Items:	N/A	
<b>Topic: Statutes</b>		
Brief Discussion:	<p>Dr. Ruffridge states that HB 306 to extend the board of pharmacy passed the legislature. Dr. Ruffridge states HB 145 also passed to expand pharmacist's authority; updates "independent administration" with "prescribe", addresses cooperative practice agreements, and insurance reimbursement. Ms. Carrillo states that regulations to implement HB 145 are due in July 2023. Dr. Ruffridge states SB 132 to exempt the Board of Veterinary Examiners from participation with the PDMP did not pass. Dr. Schaber states SB 210 related to pharmacy benefits managers and cost-savings to patients was a bill of interest but board did not take official position. The bill did not make to a committee hearing. Dr. Schaber states it relates to white and brown bagging, which were discussed by the board previously (patient choice).</p> <p>Dr. Ruffridge states the board should prepare a list of statutes to put forward for next session. Ms. Carrillo referred to preliminary list in the board's draft FY2022 annual report. Dr. Schaber agrees a subcommittee would be helpful.</p> <p>Off record at 10:55 a.m. for break. On record at 11:02 a.m. from break.</p>	
Motion:	N/A	
Recorded Votes:	N/A	

Action Items:	N/A
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**Topic: Pharmacy Locker Demo (Kiosks; Bryan Rigney)**

<p>Brief Discussion:</p>	<p><i>Mr. Rigney provides a demo on use of a pharmacy locker (kiosk); product is called iLocalBox. Mr. Rigney states it is an alternative to mail order pharmacy services, is secure, contactless, and a convenient way to increase patient access to medications and improve adherence; extends the reach of community pharmacies.</i></p> <ul style="list-style-type: none"> <li>• <i>Safety and security: temperature-controlled system, complete chain of custody tracking, surveillance and alarm systems, package sensor technology, encryption, locking mechanisms.</i></li> <li>• <i>Accuracy: single stock, prescriptions still checked by pharmacist, adjudication. Patient experience: contactless pick-up, no lines/waiting, order refills, telepharmacy consulting platform, self-informed notifications and reminders, ease of payment</i></li> <li>• <i>Traceability and reporting: provides complete auditability and medication retraction prior to pick-up (assignment, stocking, pick-up, expiration, etc.)</i></li> </ul> <p><i>Ramsey Bell asks to provide example of where this would be located; asks who would provide the consultation/answering services if it is a 24/hour service, e.g.: would it be pharmacist in Alaska? Mr. Rigney states it is up to the client.</i></p> <p><i>Ashley Schaber asks temperature control. Mr. Rigney states iLocalBox provides options for clients to set temperature thresholds; if temperatures cross thresholds, medication can be put on hold so patient cannot pick up. Ms. Carrillo asks about error rate and how often temperatures have crossed thresholds. Ms. Carrillo also asks about how a pharmacy may have their locker serviced. Mr. Rigney states there has been no instance of temperature failure since implementation; iLocalBox provides maintenance for servicing.</i></p> <p><i>Justin Ruffridge comments on licensure requirement for individuals servicing the state. Mr. Rigney responds that the company will defer to client.</i></p> <p><i>for clients to set temperature thresholds; if temperatures cross thresholds, medication can be put on hold so patient cannot pick up. Ms. Carrillo asks about error rate and how often temperatures have crossed thresholds. Ms. Carrillo also asks about how a pharmacy may have their locker serviced. Mr. Rigney states there has been no instance of temperature failure since implementation; iLocalBox provides maintenance for servicing.</i></p> <p><i>Justin Ruffridge comments on licensure requirement for individuals servicing the state. Mr. Rigney responds that the company will defer to client.</i></p> <p><i>Callista Carlton states that long-term locker pick-up is a sustainable long-term solution for access to care post-COVID.</i></p>
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	<p><i>Leif Holm inquiries about placement of kiosks in relation to the location of the pharmacy.</i></p> <p><i>Justin Ruffridge asks about the difference between a kiosk (locker) and an automated dispensing cabinet. Mr. Rigney states the kiosks are distinct from automated cabinets as it does not perform pill counts. Dr. Ruffridge asks about states which differentiate between lockers and cabinets. Mr. Rigney references Oregon. Ms. Carrillo states kiosks rules can be implemented in regulation; the board may specify placement requirements. Ms. Carrillo states licensing of automated dispensing cabinets requires legislation.</i></p>
Motion:	N/A
Recorded Votes:	N/A
Action Items:	N/A
<b>Topic: Board Business (annual report, 2023 strategic plan, application review, subcommittees, position statements, crisis stabilization units)</b>	
Brief Discussion:	<p><i>Ms. Carrillo provides an overview of the draft annual report, including highlights in the previous year and projects to follow in FY2023. Ms. Carrillo summarizes legislative and regulatory removals, amendments, and additions, including a high-level summary of changes needed to implement HB 145 by next summer. Justin Ruffridge and Ramsey Bell notes corrections needed on the annual report regarding board membership details.</i></p> <p><i>Ms. Carrillo provides an overview of the board’s strategic plan, which adds strategies around the DSCSA and system integrations to improve licensing and administrative functions. The board reviews emergency and regular applications, collaborative practice agreements, and DEA 106 forms.</i></p> <p><i>Ms. Sherrell explains the need for the board to address 42 CFR Part 2 related to medication assisted treatment; suggests a subcommittee to bring opioid treatment providers and office-based providers together to the table for input. Ms. Sherrell adds she has been meeting with a number of providers around this topic and the collection of its data in the PDMP. Ms. Sherrell states it is a complex matter and should involve stakeholders, including a representative from the Board of Pharmacy. Ms. Carrillo reiterates that Department of Law has opined the board is required to issue regulations. Ms. Carrillo states the subcommittee can help facilitate development of regulations.</i></p> <p><i>The board reviewed correspondence from Dr. Andre Neptune regarding crisis stabilization unit. Ms. Carrillo recalls a legal opinion previously provided on alternative care sites. Dr. Ruffridge agrees this may be related, but requests follow-up to clarify types of services being provided.</i></p>
Motion:	<ul style="list-style-type: none"> <li>• <i>Ashley Schaber motions to approve the board’s FY2022 annual report as amended and the 2023 strategic plan as written, seconded by Ramsey Bell, and approved unanimously, it is:</i></li> </ul> <p style="text-align: center;"><i>RESOLVED to approve the FY2022 Annual Report as amended and 2023 Strategic Plan as written.</i></p>

- *On a motion duly made by Ashley Schaber in accordance with AS 44.62.310(c)(2) and seconded by James Henderson, the board unanimously moves to enter executive session for the purpose of discussing subjects that tend to prejudice the reputation and character of any person, provided the person may request a public discussion.*

*RESOLVED to enter into executive session in accordance with AS 44.62.310(c)(2). Staff, Laura Carrillo and Bradley Johnson are authorized to remain in the room.*

*Off record at 12:13 p.m.*

*On record at 1:06 p.m.*

- *Ashley Schaber motions to approve the technician license application, 187538, for Marlene Rivas, seconded by Ramsey Bell, and approved unanimously with one absence with James Henderson, it is:*

*RESOLVED to approve the application for Marlene Rivas.*

- *Ashley Schaber motions to approve the collaborative practice agreement for Providence Kodiak Island Medical Center - #144054, seconded by Ramsey Bell, and approved unanimously, it is:*

*RESOLVED to approve the collaborative practice agreement for Providence Kodiak Island Medical Center.*

- *Ashley Schaber motions to table the wholesale drug distributor application for BWXT Medical Ltd. pending additional information on jurisdiction, seconded by Ramsey Bell, and tabled unanimously, it is:*

*RESOLVED to table the wholesale drug distributor application for BWXT Medical Ltd.*

- *Ashley Schaber motions to table the two shared services applications for Pipeline Rx pending additional guidance from the division, seconded by Ramsey Bell, and tabled unanimously, it is:*

*RESOLVED to table the shared pharmacy services applications for Pipeline Rx.*

- *Ashley Schaber motions to create a subcommittee to implement 42 CFR Part 2, seconded by James Henderson, and approved unanimously, it is:*

*RESOLVED to create a subcommittee for 42 CFR Part 2.*

Recorded Votes:

*Justin Ruffridge*

*James Henderson*

*Ashley Schaber*

	Ramsey Bell	
	Leif Holm	
Action Items:	<p><i>Ms. Carrillo will distinguish between kiosks and automated dispensing cabinets in the annual report and will post the annual report to the board's website.</i></p> <p><i>Ms. Carrillo will see whether defining "jurisdiction" is in statute or regulation. Language in law book seems to imply to applicants outside of Alaska but within the U.S.</i></p> <p><i>Ms. Carrillo will post the FY 2023 Strategic Plan to the board's website.</i></p> <p><i>Ms. Carrillo will notify emergency permit applicants that they do not qualify; instruct them to apply for permanent license.</i></p> <p><i>Ms. Carrillo will process the collaborative practice agreement for Providence Kodiak Island Medical Center.</i></p> <p><i>Ms. Carrillo will request a legal opinion regarding jurisdiction of foreign applicants.</i></p> <p><i>Ms. Carrillo will follow-up with Costco pharmacy #10, PHAR339, on employee CS theft.</i></p> <p><i>Ms. Schaber and Ms. Sherrell will convene as part of the 42 CFR Part 2 Subcommittee.</i></p> <p><i>Ms. Carrillo will follow-up with Dr. Neptune on crisis stabilization units to clarify what specific pharmacy services will be provided.</i></p> <p><i>Ms. Carrillo will add technician and intern licenses/ability to expire license upon request with approval by the EA as a new regulation project for the September 2022 meeting; possible amendment to language requiring technician license to be returned.</i></p>	
<b>Topic: Budget Report</b>		
Brief Discussion:	<p><i>Ms. Dumas reviewed the board's fee analysis incorporating regulation of pharmaceutical manufacturers. The proposed fee is \$550, consistent with the initial and renewal fees for other facilities, including non-resident wholesale drug distributors, outsourcing facilities, and 3PLs. Ms. Dumas shares the division may anticipate around 170 wholesaler applications; Ms. Carrillo states this number comes from the number of current wholesalers the board licenses and the national ratio of wholesalers to pharmaceutical manufacturers (8:1). Ms. Carrillo adds that the board currently regulates manufacturers as wholesalers, which is inconsistent with DSCSA rules.</i></p> <p><i>James Henderson motions to concur with division's proposal and receives unanimous support.</i></p>	
Motion:	N/A	
Recorded Votes:	N/A	
Action Items:	<i>Ms. Carrillo will coordinate with Ms. Dumas and regulations specialist, Jun Maiquis, on implementing manufacturer regulations concurrent with the new fees.</i>	
<b>Topic: Subcommittee Updates</b>		
Brief Discussion:	<p><i>CSAC – Ms. Lindemuth no longer with the board; to be chaired by Dr. Ruffridge.</i></p> <p><i>PDMP chairs – no longer meeting (tabled)</i></p> <p><i>Pharmacy well-being subcommittee: Ashley Schaber recalls this has not officially been formed, but that she and Ms. Carrillo reached out to the Department of Labor on</i></p>	

	<p><i>collaboration. Ms. Carrillo shares that the Dept. of Labor would not participate but could provide data on employment trends. Ms. Carrillo shares there is a well-being index survey that is distributed by the NABP for Alaska's district.</i></p> <p><i>Compounding subcommittee (tabled)</i></p>	
Motion:	<ul style="list-style-type: none"> <li><i>Ashley Schaber motions to create a subcommittee to implement a Pharmacy Well-Being Subcommittee, seconded by Ramsey Bell, and approved unanimously, it is:</i></li> </ul> <p style="text-align: center;"><i>RESOLVED to create a subcommittee for pharmacy well-being.</i></p>	
Recorded Votes:	<i>Justin Ruffridge</i>	<i>James Henderson</i>
	<i>Ashley Schaber</i>	
	<i>Ramsey Bell</i>	
	<i>Leif Holm</i>	
Action Items:	<i>Ashley Schaber and Ramsey Bell will convene for the Pharmacy Well-Being Subcommittee.</i>	
<b>Topic: Industry Updates</b>		
Brief Discussion:	<p><i>Brandy Seignemartin (AKPhA): supporting federal efforts for PBM regulation (SB 293); asking Sen. Sullivan to sign off on the federal legislation because he is part of the commerce committee. PBM regulation is critically important; working on it at the state level also incorporates white and brown bagging (patient choice). Dr. Seignemartin expresses interest in participating in the well-being subcommittee. participate in well-being subcommittee.</i></p> <p><i>Dr. Seignemartin shares that the association's annual leadership summit is September 23-24, 2022 and shares there is an upcoming webinar on pediatric vaccination approval on July 23, 2022. Also shares there is a student pharmacist rotation opportunity and that the preliminary schedule for the Annual Meeting is February 17-19, 2023.</i></p> <p><i>Ms. Carrillo states the board's September meeting may conflict with the leadership summit and suggests the board could reschedule.</i></p>	
Motion:	<i>N/A</i>	
Recorded Votes:	<i>N/A</i>	
Action Items:	<i>N/A</i>	
<b>Topic: Regulations</b>		
Brief Discussion:	<p><i>Ms. Carrillo shares that regulations related to military permits, emergency permits, executive administrator duties, and renewal will take effect on July 7, 2022. Ms. Carrillo also shares that the public comment period for the board's large regulation project ended June 13, 2022; comments are included in the board's packet for review.</i></p> <p><i>The board expresses concern about the State Medical Board's corresponding regulations (12 AAC 40.983) to 12 AAC 52.240 dealing with cooperative/collaborative practice agreements. Several members of the board express a desire to peel off this regulation until the language in 12 AAC 40.983 and concerns around the physical exam</i></p>	

	<p><i>requirement is resolved. Ms. Carrillo suggests a subcommittee to include a representative from the Medical Board.</i></p> <p><i>The board discusses new regulations to release for public comment (FY 2023 regulations), including veterinary reporting to the PDMP.</i></p> <p><i>The board discusses regulations to pursue in FY2023, including regulations to implement HB 145.</i></p>	
<p>Motion:</p>	<ul style="list-style-type: none"> <li>• <i>Ashley Schaber motions to adopt the large regulations project as presented at the June 16, 2022, with review of public comments received through June 13, 2022, except for the proposed amendments to 12 AAC 52.240. With the motion seconded by James Henderson, and approved unanimously, it is:</i></li> </ul> <p><i>RESOLVED to adopt the proposed changes to the following regulations as publicly noticed: 12 AAC 52...</i></p> <p><i>.020, .030, .040, .070, .080, .092, .095, .120, .130, .140, .200, .230, .470, .585, .620, 635, .696, .697, .860, .865, and .990.</i></p> <ul style="list-style-type: none"> <li>• <i>James Henderson motions to remove 12 AAC 52.865(b)(2), seconded by Leif Holm, and approved with one abstention by Justin Ruffridge.</i></li> </ul> <p><i>RESOLVED to remove 12 AAC 52.865(b)(2) in the draft for FY2023 regulations.</i></p> <ul style="list-style-type: none"> <li>• <i>Justin Ruffridge motions to establish a regulations subcommittee, seconded by James Henderson, and approved unanimously, it is.</i></li> </ul> <p><i>RESOLVED to establish a regulations subcommittee.</i></p>	
<p>Recorded Votes:</p>	<p><i>Justin Ruffridge</i></p>	<p><i>James Henderson</i></p>
	<p><i>Ashley Schaber</i></p>	
	<p><i>Ramsey Bell</i></p>	
	<p><i>Leif Holm</i></p>	
<p>Action Items:</p>	<p><i>Ms. Carrillo will add uniformed service (coast guard and public health service) regulations to the September 2022 meeting.</i></p> <p><i>The board will address 12 AAC 52.865(h) at the September 2022 meeting.</i></p> <p><i>The regulations subcommittee will look at all FY 2023 regulations in advance of the September 2022 meeting.</i></p> <p><i>Ms. Carrillo sign the adoption order for the large regulations project and send it to Mr. Maiquis.</i></p>	
<p><b>Topic: Administrative Update</b></p>		

Brief Discussion:	<p><i>Ms. Carrillo provides overview of Governor’s Administrative Order regarding license priorities, shares update on missing annual reports from out-of-state pharmacies, provides update on renewal forms and revisions, and reviews the board’s task list since November 2021.</i></p> <p><i>No motions or action items.</i></p>
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Next Meeting:	September 22 – 23, 2022
Adjournment:	4:32 p.m.